Exhibit 43

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben in Support of Defendants' Joint Motion for Partial Summary Judgment

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

MANAGED PHARMACY CARE, a California corporation; INDEPENDENT LIVING CENTER OF SOUTHERN CALIFORNIA, INC., a California corporation; GERALD SHAPIRO, Pharm.D., doing business as Uptown Pharmacy & Gift Shoppe; SHARON STEEN, doing business as Central Pharmacy; and TRAN PHARMACY, INC., a California corporation,

Plaintiffs,

v.

DAVID MAXWELL-JOLLY, Director of Department of Health Care Services of the State of California,

Defendant.

CV09-0382-CAS (MANx)

DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Date:
Time:
Courtroom:
Judge: The Honorable Christina A. Snyder
Trial Date: TBA
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INTRODUCTION

On September 20, 2008, the Governor signed into law AB 1183, a 5% payment reduction to pharmacies and other service providers participating in the

Medi-Cal fee for services program. AB 1183 is effective on March 1, 2009. This bill included various amendments and additions to the California Welfare and Institutions Code (W&I). AB 1183 enacted new W&I section 14105.191 and amended W&I section 14105.19 to provide that the 10% reduction in payments for various services covered under the Medi-Cal program, including payments to pharmacies, imposed by AB 5, would end on March 1, 2009. Instead of the 10% payment reduction, new section W&I 14105.191 provides for a 5% payment reduction for some services, effective March 1, 2009.

As this Court is aware, there have been a flurry of lawsuits filed as a result of the Medi-Cal payment reductions. In a lawsuit pending in this Court contesting AB 5 [hereinafter *ILC* AB 5][1/], this court granted Plaintiffs' third motion for preliminary injunction to prevent Defendant (hereinafter Department) from enforcing the 10% payment reduction. The injunction was granted after Plaintiffs appealed this Court's denial of Plaintiffs' first motion for preliminary injunction. The initial denial was based on this Court's ruling that Plaintiffs could not bring suit under the *Shaw*[2/] Supremacy Clause doctrine. In other words, the issue was whether Plaintiffs' claim of preemption should be dismissed at the initial pleading stage. The Ninth Circuit ruled it should not.[3/]

It is worth repeating that the only issue in front of the Ninth Circuit in *ILC* AB5 was "whether ILC may maintain a valid cause of action to enjoin implementation of AB 5 on the basis of federal preemption." *Independent Living Center*, 543 F. 3d. at 1055. As will be shown in the Department's opposition: (1) Plaintiffs have failed to meet their burden that the 5% payment reduction is an

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1. *Independent Living Center of Southern California et al., v. Sandra Shewry et al.,* Case no., CV 08-3315 CAS (MANx).

2. *Shaw v. Delta Airlines, Inc.,* 463 U.S. 85 (1983).

3. *Independent Living Center of Southern California et al., v. Sandra Shewry et al.* 543 F.3d 1050 (9th Cir. 2008).

"obstacle" to the accomplishment of 42 U.S.C. §1396a(a)(30)(A); and (2) Plaintiffs have failed to establish a strong likelihood of success on the merits and irreparable harm. Therefore their motion for preliminary injunction must be denied.

STATUTORY BACKGROUND

Congress created the Medicaid program in 1965 as a purely voluntary program in which states could elect to receive federal funds in exchange for providing medical services to certain individuals statutorily defined as "needy." See generally 42 U.S.C. §§ 1396 et seq.; *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990). States use federal Medicaid funds to reimburse a portion of the expenditures incurred by service providers. In exchange for federal funding, states must meet certain statutory and regulatory conditions. *See Schweiker v. Gray Panthers*, 453 U.S. 34, 37 (1981). If a state is unable or unwilling to satisfy these conditions, it may (i) voluntarily withdraw from the Medicaid program, (ii) seek a waiver from the Secretary of the U.S. Department of Health and Human Services, which administers the Medicaid program, *see*, e.g., 42 U.S.C. § 1396n, or (iii) risk federal penalties, including the withholding of some or all of its federal funding. *See id.*, § 1396c.

The most significant rule requirement for federal Medicaid funding is that states submit for federal approval a "plan for medical assistance." 42 U.S.C. § 1396a(a). The State Plan contains a comprehensive statement of the nature and scope of the state's Medicaid program, and includes the state's scheme for reimbursing service providers. *See Wilder,* 496 U.S. at 502. As codified, section 1396a(a) of the Medicaid Act includes 71 sub-parts describing the procedural and substantive requirements for State Plans. *See* 42 U.S.C. §§ 1396a(a)(1)-(71). Plaintiffs' allegations center on subpart section 1396a(a)(30)(A). The full text follows:

42 U.S.C. § 1396a(a):

> A State plan for medical assistance must, (30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

A state must obtain federal approval of its Medicaid Plan, *see* 42 U.S.C. § 1316(a), and must submit for federal approval a proposed State Plan amendment whenever the state intends to make a significant change to its practices or procedures. *See* 42 C.F.R. § 430.12. Proposed amendments to a State Plan must be submitted by the last day of the fiscal quarter in which the change occurs. *See* 42 C.F.R. §§ 430.20(b)(2), 447.256. So long as the proposed amendment is timely submitted, a state need not wait for federal approval before the policy change takes effect. If the federal government rejects part or all of a state's proposed State Plan or any amendment to that Plan, the state may be disqualified from receiving some or all of its federal Medicaid funds. *See* 42 U.S.C. § 1396c. Similarly, if a state fails to timely submit a proposed Plan or amendment, or if its actual practices deviate from the scheme set forth in its Plan, it risks losing its federal funding. *See id.*

By its terms, the Social Security Act, which includes the federal Medicaid Act, does not itself confer a cause of action, and whether a particular statute is judicially enforceable is dependent on whether it confers "rights" that are enforceable under 42 U.S.C. §1983. *Edelman v. Jordan,* 415 U.S. 651, 673-674 (1974), *Maine v. Thiboutot*, 448 U.S. 1, 7 (1980). Thus the Medicaid Act, itself, provides no recourse or remedy for private individuals or entities to challenge a State's Plan or to assert that a state's actual practices deviate from that Plan. *See Wilder*, 496 U.S. at 521. That is why the Supreme Court in *Wilder* evaluated in some detail whether the particular Medicaid statute in that case conferred

enforceable "rights" under section 1983. Otherwise, Congress provided only one mechanism to address state violations of the statute and accompanying regulations: termination of some or all of the state's federal Medicaid funding following an administrative process. *See id.*; 42 U.S.C. § 1396c. These penalties are not mandatory. The Center for Medicare & Medicaid Services (hereinafter CMS), the federal agency within the U.S. Department of Health and Human Services that administers the Medicaid program, has the power to impose, refuse to impose, reduce, or rescind these financial penalties in its administrative discretion. *See generally Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981). In addition, states may seek a waiver from CMS to excuse what might otherwise be deemed a statutory violation. *See*, e.g., 42 U.S.C. § 1396n(f). Disputes between a state and CMS over the adequacy of a State Plan, amendment, or the state practices and procedures pursuant thereto, need not result in the termination of federal funds, and often do not.

Since the enactment of the Medicaid Act in 1965, Congress has expressly considered how much discretion to afford states in setting reimbursement rates, and whether to immunize states from private challenges to the rates they set. During this early period, federal regulators retained primary authority for determining whether a state's reimbursement rates satisfied federal requirements. But in 1981, Congress passed what became known as the Boren Amendment, which transferred primary rate-setting authority from federal regulators to the states. The Boren Amendment required a State Plan to provide for payments. In so doing, Congress intended to give states more flexibility in how they set rates and manage costs, and to discourage challenges from providers. *Evergreen Presbyterian Ministries Inc. v. Hood*, 235 F.3d 908, 919 n.12 (5th Cir. 2000).

The Supreme Court nonetheless held that providers had rights under the Boren Amendment pursuant to section 1983 to challenge the adequacy of a state's reimbursement rates under the Medicaid statute. *See Wilder*, 496 U.S. at 502-03.

In response to *Wilder*, Congress repealed the Boren Amendment in 1997. (Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4712(c), 111 Stat. 509 (1997)). By repealing the Boren Amendment, Congress sought not only to reverse *Wilder* but to preclude any providers from challenging rates under the Medicaid Act. *See* FN 8 to this Opposition.

ARGUMENT

I

AB 1183 DOES NOT PRESENT AN OBSTACLE TO THE ACCOMPLISHMENT OF 42 U.S.C. § 1396a(a)(30)(A)

Plaintiffs' Supremacy Clause claim is based on alleged federal conflict preemption. In order to establish a strong likelihood of success on the merits in a conflict preemption action, the Plaintiffs must show that "compliance with both federal and state regulations is a physical impossibility," or that "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Pacific Gas & Elec. Co. v. State Energy Comm'n*, 461 U.S. 190, 204 (1983). Thus, Plaintiffs have the burden of proving that it is not possible for the Department to comply with both AB 1183 and 42 U.S.C. § 1396a § (a)(30)(A) (hereinafter § (a)(30)(A)), or that AB 1183 stands as an obstacle to the enforcement of § (a)(30)(A). The district court's task, in turn, is to analyze whether the Plaintiffs have met that burden.

Courts have long held that in policy areas like health care that traditionally have been occupied by the states, courts should be reluctant to find preemption unless the evidence of Congressional intent is compelling. *See Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715-18 (1985); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Plaintiffs, therefore, have the burden of submitting evidence that gives rise to a "clear" and "manifest" inference that Congress intended to displace a law in the state's traditional sphere of discretion. *Rice*, 331 U.S. at 230. Further, any ambiguities must be construed

against finding preemption, and courts should narrowly interpret the scope of Congress's "intended invalidation of state law" whenever possible. *Medtronic Inc., v. Lohr*, 518 U.S. 470, 485 (1996). "When considering preemption, no matter which type, 'the purpose of Congress is the ultimate touchstone.'" *Ting v. AT&T*, 319 F.3d 1126, 1136 (9th Cir. 2003), citing *Cipollohne v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

And when, as here, a plaintiff seeks to enjoin a government agency, "his case must contend with the well-established rule that the Government has traditionally been granted the widest latitude in the dispatch of its own internal affairs." *Rizzo v. Goode*, 423 U.S. 362, 378-79 (1976). This "well-established rule" bars federal courts from interfering with non-federal government operations in the absence of facts showing an immediate threat of substantial injury. *Hodgers-Durgin*, 199 F.3d 1037, 1042-43 (9th Cir. 1999); *Midgett v. Tri-County Metropolitan Transp. Dist. of Oregon*, 254 F.3d 846, 850 (9th Cir. 2001).

Plaintiffs' claim must fail as a matter of law. Plaintiffs bear the burden of demonstrating that the payment reduction of AB 1183 poses an "obstacle" so great to Congressional purpose that Congress must have impliedly intended to preempt it. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *Jimeno v. Mobil Oil. Corp.*, 66 F.3d 1514, 1526 n.6 (9th Cir. 1995).[4/]

First, the Medicaid Act creates no substantive limitations regarding Medicaid rates that are capable of being violated and therefore an "obstacle" to Congress's purpose, but merely sets policy objectives that are not judicially enforceable. By its terms, § (a)(30)(A) merely governs the content of the State Medicaid Plans, and requires that they "provide such methods and procedures" to "assure that payments [to providers] are consistent with efficiency, economy, and

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4. Courts recognize other doctrines to determine Congressional intent, such as express preemption, field preemption, and impossibility preemption, *see generally English v. General Electric Co.*, 496 U.S. 72 (1990).

quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area [equal access]."

To the extent that § (a)(30)(A) could be construed as having significance beyond the mere contents of a State Plan, which the Department disputes, it does not mandate that the state pay any set minimum, or that the State, for example, cover a given providers' costs. *See Evergreen*, 235 F.3d at 929; *Folden v. Washington State Department of Social and Health Services*, 744 F.Supp. 1507, 1523-24 (W.D. Wash. 1990). Ultimately, state policymakers and the federal agency that regulates them must strike the appropriate balance.

Even if the state's rates fall short of federal requirements, which is not the case here, there is no "obstacle" to Congressional purpose, when Congress expressly contemplated such shortcomings and established a detailed regulatory regime to deal with them. Congress expected that some states might at times strike the wrong balance between beneficiary services and cost controls, as plaintiffs allege in this case. *See Sanchez*, 416 F.3d at 1059-60. However, Congress did not intend to presumptively preempt states from enacting such laws and regulations. Instead, Congress established a "complementary administrative framework" to deal with them. *New York Dept. of Social Services v. Dublino*, 413 U.S. 405, 421 (1973).

An injunction should not issue where the court's order itself would present an "obstacle" to Congress's purpose. Ultimately, the "purpose of Congress is the ultimate touchstone" under the preemption doctrine. *Retail Clerks Int'l Ass'n Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963). Plaintiffs bear the burden of proof, *see Jimeno*, 66 F.3d at 1526 n.6, which on this motion requires them to produce at least some evidence of Congressional intent in support of preemption.

Plaintiffs' burden is particularly onerous in this case because they must

overcome both the judicially recognized presumption against preemption in cases involving health, safety, and welfare and the legislative history relating to the repeal of the Boren Amendment which suggests that Congress's intent was to foreclose provider suits rather than permit them. The legislative history confirms that, rather than advancing Congress's intent, an order granting an injunction in this case would undermine, rather than effectuate, Congressional intent. Accordingly, the Court should dismiss Plaintiffs' challenge to the adequacy of rates under the Medicaid Act as a matter of law.

As the Court is aware, there are three components to a preliminary injunction: (1) Plaintiffs need to establish a strong likelihood of success on the merits; (2) the balance of irreparable harm favors Plaintiffs; and (3) that the public interest favors granting the injunction. *See Aleknagik Natives Ltd. v. Andrus*, 648 F.2d 496, 501 (9th Cir. 1980).

Under an alternative test, a preliminary injunction may issue upon a clear showing of either: (1) probable success on the merits and possible irreparable injury; or, (2) sufficiently serious questions going to the merits to make them fair ground for litigation, and a balance of hardships that tips decidedly toward the party requesting the preliminary relief. *Benda v. Grand Lodge of Int' l Ass'n*, 584 F.2d 308, 314-315 (9th Cir. 1978). In order to be entitled to an injunction, Plaintiffs must make a showing that they face a real or immediate threat of substantial or irreparable injury. *Hodgers-Durgin,* 199 F.3d at 1042.

Moreover, any injunction that prevents implementation of a state statute, whether a TRO, preliminary injunction, or permanent injunction, *per se* inflicts irreparable injury to the public interest. As the court stated in *Coalition for Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997), "a state suffers irreparable injury whenever an enactment of its people or their representatives is

enjoined."[5/] Because an injunction against lawfully-enacted state legislation constitutes irreparable harm to the State and the public, *per se*, the district court must weigh the harm to the State against whatever showing the Plaintiffs made as to their threatened harm.

II

THE DEPARTMENT HAS CONDUCTED A REASONABLY PRINCIPLED ANALYSIS AND CONCLUDED THAT REIMBURSEMENT PURSUANT TO AB 1183 WILL COMPLY WITH 42 U.S.C. SECTION 1396a(a)(30)(A)

Under the Boren Amendment, judicial review was "limited to a determination of whether the state action is arbitrary and capricious or contrary to law." *Folden*, 744 F. Supp. at 1525. The Boren Amendment imposed a much stricter requirement on the kind of analysis States must conduct. It expressly required rates to be "reasonable and adequate" to "meet" efficient and economically operated provider costs, and expressly required states to make "findings" that such rates were reasonable and adequate. However, even the Boren Amendment did not require a formal rate study or written findings.

In *Folden v. Washington State DSHS*, 981 F. 3d 1054 (9th Cir. 1992), the district court correctly noted that the procedural requirements of the federal regulation are satisfied if the state agency has engaged in a bona fide fact-finding process. The district court noted that the states are free to create their own methods of arriving at the required findings and that the findings process does not require any special studies or written findings. It is sufficient if the state agency has considered, on the basis of some reasonably principled analysis, whether its

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5. As *Coalition for Economic Equity* further explained: "Balancing the equities, we are persuaded that the State has demonstrated the clear possibility of irreparable injury to its citizens if a stay of the mandate is granted; it is clear that a state suffers irreparable injury whenever an enactment of its people or their representatives is enjoined. *See New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345 (1977) (Rehnquist, J., in chambers) ("It also seems to me that any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury."); *see also Campbell v. Wood*, 20 F.3d 1050, 1051 (9th Cir. 1994).

payment rates meet the substantive requirements of the Boren Amendment. *Id.* at 1057.

In this case, the state agency has gone even beyond what was required under the stricter Boren Amendment by not only doing a reasonably principled analysis, but incorporating it into a formal written Analysis of Pharmacy Reimbursement under AB 1183. *See* Douglas Decl., ¶11; Ex. A-A, AB 1183 Analysis.

It is public knowledge that the State is experiencing an unprecedented financial crisis, with a projected budget deficit of over $40 billion. *See* Douglas Decl. ¶ 13 Ex. A. In times of unprecedented fiscal and budgetary crisis, policymakers must exercise their judgment to balance competing federal objectives in the best interests of Medi-Cal patients and the residents of California. Congress afforded California "substantial discretion" to do so. *Alexander v. Choate*, 469 U.S. 287, 303 (1985); 42 U.S.C. § 1396a(a)(18). According to policymakers, the rate reductions promote efficiency within the Medi-Cal system; enhance the long-term fiscal health of the program; and avoid far more painful cuts to the program (such as cutting optional services or restricting eligibility) that could curtail care for current beneficiaries. *See* Exhibit A-A, AB 1183 Analysis. As noted in the Department's AB 1183 analysis:

> The Legislature had other alternatives for reducing spending in the Medi-Cal program, which would have had a much more negative impact on Medi-Cal recipients. For example, the Legislature could have eliminated Medi-Cal coverage for various optional services, that states are not required by federal law to cover. These optional services include, but are not limited to, prescription drugs, adult day health care services and adult dental services. For example, the Medi-Cal program currently pays pharmacies approximately $2.9 billion annually for drugs. Thus, the state could have achieved much greater budgetary savings by simply eliminating Medi-Cal coverage of prescription drugs. The Legislature could have also achieved greater savings by imposing stricter eligibility requirements, that would have eliminated Medi-Cal coverage altogether for some recipients. In an effort to achieve some reduction in Medi-Cal expenditures in the State''s Budget, the Legislature and Governor chose moderate provider payment reductions, rather than many measures that could have had a detrimental impact on many Medi-Cal recipients.

See Douglas Decl. Ex. A; Exhibit A-A, AB 1183 Analysis, p. 4.

Instead of paying pharmacies approximately $3.2 billion annually ($2.9 billion for drugs), the Medi-Cal program will be paying them approximately $3 billion annually ($2.75 billion for drugs). *See* Douglas Decl. Ex. A ¶ 10. The analysis further concluded that Medi-Cal reimbursement would comply with all applicable requirements related to the "efficiency, economy, and quality of care" (hereinafter EEQ) provision. *See* Douglas Decl. Ex. A, pp. 3-10. The Analysis concluded that reduced reimbursement pursuant to AB 1183 will compensate a higher portion of pharmacy costs even above the "range of reasonableness" required by the stricter Boren Amendment. *Id.* at 5-10. The analysis concluded that recipients should continue to have sufficient access to Medi-Cal covered drugs and other pharmacy services when the 5% payment reduction is implemented on March 1, 2009. *See* Ex. A-A, AB 1183 Analysis, pp. 10-12. Thus, "the payment reduction results in more efficient and economic administration of the program while assuring that the interests of Medi-Cal recipients are maintained." *Id.* at p. 5.

The analysis determined that recipients should continue to have sufficient access to Medi-Cal covered drugs and other pharmacy services when the 5% payment reduction is implemented on March 1, 2009. *See* Ex. A-A, AB 1183 Analysis, pp. 10-14; Ex. C, Gorospe Decl., ¶¶ 5-10; Ex. D, Flores Decl., ¶¶ 4-7.

This Court's ruling granting the third preliminary injunction in *ILC* AB5 held that "when *the State of California* seeks to modify reimbursement rates for health care services provided under the Medi-Cal program, it must consider efficiency, economy, quality of care, and equality of access, as well as the effect of providers' costs on those relevant statutory factors."[6/] The Department thoroughly considered EEQ and access, and as noted in the Analysis:

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6. The Department does not concede that it must conduct a written analysis of EEQ prior to a payment reduction, or of the effect of provider's costs.

> After a 5% payment reduction is implemented on March 1, 2009, Medi-Cal reimbursement paid to pharmacies will comply with title 42, United States Code, section 1396a(a)(30)(A). The available data indicates that Medi-Cal recipients will continue to have sufficient access to pharmacy services as required by federal law. Reimbursement will be below applicable federal upper payment limits. The 5% payment reduction will result in more efficient and economical Medi-Cal coverage. It will not have any negative impact for Medi-Cal recipients. Finally, the Department determined that Medi-Cal reimbursement will in the aggregate compensate pharmacy drug costs at a level that is well above the "range of reasonableness" that was acceptable under the repealed Boren Amendment. Thus, reimbursement will be sufficient under the more flexible requirements of section 1396a(a)(30)(A).

See Ex. A-A, AB 1183 Analysis, pp. 12-13.

In part, the analysis relied on the Myers and Stauffer survey of dispensing and acquisition costs of pharmaceuticals in California. *See* Exhibit A-A. On pages 5-10 of the analysis report, the effect of the 5% payment reduction is analyzed to determine the aggregate Medi-Cal reimbursement for various drugs. The aggregate Medi-Cal reimbursement for all drugs is 103% of pharmacy costs after the 5% payment reduction. This is significantly higher than the acceptable range of reasonableness under the repealed Boren Amendment which was 85%-95% ; the aggregate Medi-Cal reimbursement for all single source drugs is 98-99% of pharmacy costs after the 5% payment reduction; the aggregate Medi-Cal reimbursement for multi-source drugs ranges from 107% to 137% of pharmacy costs after the 5% payment reduction. *See* Ex. A-A, AB 1183 Analysis, pp. 8-12; Ex. C, Gorospe Decl., ¶¶ 9, 22.

Since a detailed analysis of EEQ was performed by the Department, Plaintiffs cannot establish a strong likelihood of success on the merits. As a result, this Court does not need to address the second component of a preliminary injunction request, irreparable harm. *Global Horizons, Inc., v. United States DOL*, 510 F.3d. 1054, 1058 (9th Cir. 2007).

However, even if Plaintiffs' allegations of irreparable harm were considered, the conclusion of potential harm would be speculative at best.

Speculative injury does not constitute irreparable injury sufficient to warrant granting a preliminary injunction. *Goldie's Bookstore Inc., v. Super Ct.,* 739 F.2d 466, 472 (9th Cir. 1984). Plaintiffs must do more than merely allege imminent harm sufficient to establish standing; they must demonstrate immediate threatened injury as a prerequisite to preliminary injunctive relief. *L.A. Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1201 (9th Cir. 1980).

The declarations submitted by Plaintiffs, the majority of whom are Medi-Cal providers, run the gamut on how their businesses allegedly will be affected by the 5% payment reduction. Much of the speculative injury mirrors what was asserted in *ILC* AB5. As alleged, some Plaintiffs may stop providing Medi-Cal services, others will stop, and all allege that their profitability will be adversely impacted by AB 1183. However, their proposed testimony is speculative and disputable. *See* Ex. C, Gorospe Decl., ¶¶ 11-23; Ex. C-A. All of them also speculate as to how Medi-Cal beneficiaries would be harmed in some fashion. Declarant David Medina takes it a step further by stating, "I may cut the business hours of the pharmacy or layoff employees to remain a profitable business." *See* Medina Decl. 11:26-28. However, as the Supreme Court has stated:

> [T]he temporary loss of income, ultimately to be recovered, does not usually constitute irreparable injury. . .mere injuries, however substantial, in terms of money, time and energy necessarily expended. . .are not enough.

Sampson v. Murray, 415 U.S. 61, 90 (1974).

More importantly, however, the Department's analysis demonstrates that Medi-Cal reimbursement after a 5% reduction will compensate pharmacy costs at levels that exceed the "range of reasonableness" that was acceptable under the stricter Boren Amendment. *See* Ex. A-A, AB 1183 Analysis, pp. 5-10. Furthermore, the Department evaluated data during the time the 10% reduction of AB 5 was in place from July 1, 2008 through August 17, 2008, and found no negative impact on pharmacy participation. *See* Ex. A-A, AB 1183 Analysis, p. 5-

10, Ex. A-A(D)-(G). In other words, pharmacists are not going to shutter their businesses. *See* Ex. A-A, AB 1183 Analysis, p. 13, Ex. A-A(D)-(G); *See* Ex. C, Gorospe Decl. ¶ 10; Ex. D, Flores Decl., ¶¶ 4-7; Ex. A-A.

In the aggregate, an extremely high percentage of pharmacy costs will be compensated and the more efficient pharmacies should be able to obtain a substantial profit from providing services under the Medi-Cal program. *See* Ex. A-A, AB 1183 Analysis, p. 10; *See* Ex. C, Gorospe Decl. ¶ 17.

The third and final component of a preliminary injunction, if applicable, is whether the public interest favors granting the injunction. As noted earlier, federal courts should not interfere with non-federal government operations in the absence of facts showing an immediate threat of substantial injury. *Hodgers-Durgin*, 199 F.3d at 1042-43; *Midgett*, 254 F.3d at 850.

The State is in the midst of an unprecedented fiscal and budgetary crisis. The Legislature must exercise its judgment to balance the competing federal objectives in the best interests of Medi-Cal patients and the residents of California. Congress afforded California "substantial discretion" to do so. *Alexander*, 469 U.S. at 303, (internal quotations omitted).

At the end of the day, and as argued above, Plaintiffs have failed to meet their burden of proving a conflict between AB 1183 and § (a)(30(A) demonstrating that the payment reduction of AB 1183 poses an "obstacle." Plaintiffs cannot establish a strong likelihood of success on the merits. The Department has conducted a detailed analysis on the payment reduction and found that reimbursement under AB 1183 will comply with both the EEQ and access provision of § (a)(30)(A). Plaintiffs' irreparable harm contention is speculative at best and the public interest does not favor granting the injunction.

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III

CONGRESSIONAL INTENT UNDER 42 U.S.C. SECTION 1396a(a)(30)(A) DOES NOT CONFER AN INDIVIDUAL RIGHT TO SUE[7]

As noted previously, § (a)(30)(A) requires state Medicaid agencies to submit to CMS a State Plan that provides that "payments are consistent with efficiency, economy, and quality of care" and that there is sufficient access to providers for services. Upon approval of the State Plan, a state is eligible to receive federal funds to operate the program. If a state operates its Medicaid program in violation of its state plan or federal law, CMS may decline federal funding for such services. 42 U.S.C. § 1396c. Thus, the statutory remedy intended by Congress for any alleged violation of § (a)(30)(A) is the withholding of federal funds, not judicial enforcement.

In *Sanchez v. Johnson*, 416 F.3d 1051, the court held that Congress did not intend a judicial remedy for alleged violations of § (a)(30)(A)'s efficiency, economy, and quality of care provisions. The court specifically found that:

> Section 30(A) is concerned with a number of competing interests. It requires a State to "provide such methods and procedures . . . to assure that payments are consistent with efficiency, economy, and quality of care." The most efficient and economical system of providing care may be one that benefits taxpayers to the detriment of medical providers and recipients; likewise, the provision of "quality" care — whatever standard may be implied by such a nebulous term — is likely to conflict with the goals of efficiency and economy. The tension between these statutory objectives supports the conclusion that § 30(A) is concerned with overall methodology rather than conferring individually enforceable rights on individual Medicaid recipients. [¶] . . . *The language of § 30(A) is . . . ill-suited to judicial remedy; the interpretation and balancing of the statute's indeterminate and competing goals*

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7. The Department anticipates that Plaintiffs will argue the Department is collaterally estopped from addressing this issue pursuant to *Independent Living Center of Southern California et al., v. Sandra Shewry et al.*, 543 F.3d 1050 (9th Cir. 2008), although the facts in the instant matter are substantially different. Indeed, the only issue in front of the Court of Appeals in the *Independent Living Center* matter was "whether ILC may maintain a valid cause of action to enjoin implementation of AB 5 on the basis of federal preemption." The Department does not concede that 42 U.S.C. §1396a(a)(30)(A) confers an individual right to sue.

> *would involve making policy decisions for which this court has little expertise and even less authority.*

Id. at 1059-1060. Emphasis added.

Thus, the Ninth Circuit recognized the administrative, statutory remedy intended by Congress and acknowledged that Congress did not intend judicial enforcement for alleged violations of § (a)(30)(A)'s provisions, by finding that they are "ill-suited to judicial remedy."

In 2007, the Ninth Circuit reaffirmed *Sanchez*'s interpretation of § (a)(30)(A) as involving a "policy decision for which [a] court has little expertise and even less authority," and further stated that attempting to enforce § (a)(30)(A) "would require a court to account for numerous, largely unquantifiable variables." *Ball v. Rodgers*, 492 F.3d 1094, 1115 (9th Cir. 2007).

The above interpretation of Congressional intent finds support in Congress's express statement concerning the Social Security Act, which includes § (a)(30)(A). In enacting the Balanced Budget Act of 1997, Congress explicitly stated its intent that § 1396a should not be judicially enforced, when it repealed the Boren Amendment, which applied to hospitals and nursing facilities.[8/]

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8. The history of the repeal of the Boren Amendment illustrates Congressional intent that §(a)(30)(A) not be judicially enforced. Unlike §(a)(30)(A), the Boren Amendment expressly mentioned provider costs and expressly required states to establish reasonable cost based rates for hospitals and nursing facilities. In *Wilder v. Virginia Hospital Association*, 496 U.S. 498, the Supreme Court undertook a lengthy analysis to determine whether providers had a "right" under the Boren Amendment that would be enforceable under 42 U.S.C. § 1983, and held that the Boren Amendment did create such a "right" for providers. If providers could have simply filed an action for alleged preemption based on the Supremacy Clause, there would have been no reason for the Supreme Court to have evaluated in detail whether the Boren Amendment created such enforceable "rights" for providers. It is well-settled that the Social Security Act, which includes the Medicaid statutes, does not itself create a cause of action for anyone to challenge a state's compliance with its provisions, and whether such a provision is judicially enforceable is dependent on whether Congress intended to confer a "right" that is enforceable pursuant to 42 U.S.C. §1983. (*Edelman v. Jordan,* 415 U.S. 651, 673-674 (1974), *Maine v. Thiboutot*, 448 U.S. 1, 7 (1980), *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, and *Blessing v. Freestone,* 520 U.S. 329 (1997). The Social Security Act does not itself create a cause of action because there is no expression of Congressional intent in the Act

Plaintiffs are attempting to have this Court undercut decades of federal jurisprudence to say that, merely by claiming to be suing under the Supremacy Clause instead of § 1983, a party can obtain a remedy in federal court against a state agency for non-compliance with a provision of the Medicaid Act, when Congress has clearly, expressly, and unequivocally stated otherwise.

Congress's clear purpose would be thwarted if parties were successful in suing a state for violating § (a)(30)(A)'s provisions. With the Boren Amendment's repeal, there is no federal Medicaid statute requiring that reimbursement rates be set based on provider costs. Interpreting § (a)(30)(A) as establishing a reasonable cost based reimbursement standard that providers or others could judicially enforce would nullify Congress's intent in repealing the Boren Amendment. This would be true regardless of the vehicle used in framing the complaint, whether it is §1983 or the Supremacy Clause.

IV

THE STATE RETAINS SOVEREIGN IMMUNITY AND PLAINTIFFS' LAWSUIT IS BARRED BY THE ELEVENTH AMENDMENT

The State retains sovereign immunity under the United States Constitution against the relief Plaintiffs seek because the protection of a conferred federal right is not involved. The Eleventh Amendment reaffirmed that states have sovereign

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itself that it be judicially enforced. Thus, on that basis alone, the Social Security Act fails the four-part test for whether a federal statute creates an implied right of action, as set forth in *Cort v. Ash*, 422 U.S. 66 (1975). Even though the Social Security Act itself contains no indication of Congressional intent that the Act be judicially enforced, Congress expressly stated its intent in 42 U.S.C. §1983, that lawsuits may be filed seeking to enforce "rights" contained in the Social Security Act. *Wilder*, 496 U.S. at p. 509, n. 9. But whether a federal statute creates an implied right of action or whether it can be enforced under 42 U.S.C. §1983 "overlap in one meaningful respect - in either case [the Court] must first determine whether Congress intended to create a federal right." *Gonzaga v. Doe*, 536 U.S. 273, 283 (2002). Furthermore, if a federal statute creates no "rights" enforceable under 42 U.S.C. § 1983, then "[t]he question *whether Congress intended to create a private right of action* [is] *definitively answered in the negative. Id.* at p. 284, *quoting Touche Ross & Co. v. Redington*, 442 U.S. 560, 576 (1979) (emphasis added). Therefore, as *Gonzaga* held, if a federal statute does not create a "right" for plaintiffs, then there is *no basis for a private suit*, whether under §1983 or under an implied right of action. *Id.* (emphasis added).

immunity against federal court lawsuits seeking relief based on alleged violations of federal law. *Edelman v. Jordan*, 415 U.S. 651, 662-663; *Pennhurst State School & Hosp. v. Halderman*, 465 U.S. 88, 100 (1984); and *Alden v. Maine*, 527 U.S. 706 (1999).

However, the Supreme Court has carved out a very narrow exception for lawsuits seeking prospective injunctive relief against state officials in their official capacity, for the purpose of remedying an ongoing violation of federal law and for the purpose of protecting federal rights. *Ex parte Young*, 209 U.S. 123 (1908).

As the Ninth Circuit held in *Sanchez*, § (a)(30)(A) does not create a judicially enforceable "right" for providers or recipients. The Supremacy Clause "is not a source of any federal rights." Rather, it "secure[s] federal rights by according them priority whenever they come in conflict with state law." *Chapman* v. *Houston Welfare Rights Organization*, 441 U.S. 600, 613 (1979).

Each state is a sovereign power within the federal system, and sovereignty signifies that a state may not be amenable to suit without that state's consent. *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 54 (1996). The United States Supreme Court has consistently reaffirmed that "federal jurisdiction over suits against unconsenting States was not contemplated by the Constitution when establishing the judicial power of the United States." *Id.* (citations and internal quotation marks omitted). This rule is based on the principle that any attempt to assert federal jurisdiction over a State in a private action brought without the State's consent is barred because sovereign immunity protects against "the indignity of subjecting a State to the coercive process of judicial tribunals at the instance of private parties." *Puerto Rico Aqueduct and Sewer Authority v. Metcalf & Eddy, Inc.*, 506 U.S. 139 (1993) (internal quotation marks omitted).

Plaintiffs' remedy in the instant matter is to recover money against the State for funds above the 5% payment reduction. The Eleventh Amendment bars a lawsuit when relief must be paid from public funds in the state treasury. The

Supreme Court explained:

> [W]hen the action is in essence one for the recovery of money from the state, the state is the real, substantial party in interest and is entitled to invoke its sovereign immunity from suit even though individual officials are nominal defendants.

Ford Motor Co. v. Dep't of Treasury, 323 U.S. 459, 464 (1945).

A central objective of the Eleventh Amendment is to prevent federal court judgments that must be paid directly out of state funds. *Hess v. Port Authority Trans-Hudson Corp.* 513 U.S. 30, 48 (1994); *Quern v. Jordan*, 440 U.S. 332, 337 (1979). Any such payment constitutes damages against the state prohibited by the Eleventh Amendment. Therefore, merely labeling the requested relief as prospective is insufficient to invoke *Ex parte Young*.

Although the *Ex parte Young* doctrine allows injunctive relief that might have an ancillary effect on a state treasury, it does not allow an award for monetary relief that is the practical equivalent of money damages, even if this relief is characterized as equitable. *Edelman*, 415 U.S. at 666-668. In *Edelman*, the Supreme Court made clear that the doctrine of *Ex parte Young* permits suits for prospective injunctive relief only, and that the Eleventh Amendment prevents a federal court from awarding relief that will be paid out of the state treasury, even if the suit is brought against a state officer rather than the state itself. *Id.* The primary purpose driving this lawsuit is to obtain funds from the State above the 5% payment reduction. The effect of any grant of relief in this case is beyond just an ancillary effect on the state treasury.

Furthermore, as noted earlier, prospective injunctive relief for Plaintiffs pursuant to *Ex parte Young* is not available for a violation of § 1396a(a)(30)(A) because their federal "rights" are not involved. *See Edelman v. Jordan*, 415 U.S. 651.

In the event that Plaintiffs' Supremacy Clause challenge is upheld, the Department did not act arbitrarily and capriciously. The Department is acting in

accordance with its obligations under state and federal law and the State Plan. It is exactly this absence of wrongful conduct on the part of the Department that distinguishes the facts of this case from cases that allowed lawsuits to proceed against state officials even with substantial ancillary effects on the state treasury. *See e.g. Milliken v. Bradley*, 433 U.S. 267, 289-290 (1977) (wrongful conduct was violation of duty to desegregate). Thus, the *Ex parte Young* doctrine has no application here, and the Eleventh Amendment bars this action from proceeding against the Department.

In summary, the State retains sovereign immunity against any judicial relief, including prospective injunctive relief, for alleged violation of section § (a)(30)(A).

V

THE SEPARATION OF POWERS DOCTRINE BARS THIS COURT FROM GRANTING THE REQUESTED RELIEF

Pursuant to the of separation of powers doctrine, a court may not issue mandate to compel appropriations. Only the legislature may appropriate funds. *Hopkins v.Saunders*, 93 F.3d 522, 527 (8th Cir. 1996) (citing *Dover Elevator Co. v. Arkansas State Univ.*, 64 F.3d 442, 447 (8th Cir. 1995); CAL. CONST., art. III, § 3.

Granting Plaintiffs' preliminary injunction motion would require this Court to legislate and therefore violate the separation of powers doctrine. Neither a court nor an executive agency is permitted to revise or rewrite law to force a constitutional interpretation. This rule applies even in the case of a facial challenge.[9/]

It is clear Plaintiffs will attempt to dispute any payment reduction and is asking this Court to step into the shoes of the Legislature to determine the amount

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9. "The canon of construction that a court should strive to interpret a statute in a way that will avoid an unconstitutional construction . . . is ''not a license for the judiciary to rewrite the language enacted by the legislature.'" *Chapman v. United States* (1991) 500 U.S. 453, 464 (quoting *U.S. v. Monsanto,* 491 U.S. 600, 611 (1989)).

of any payment reduction which violates the Separation of Powers Doctrine. Granting Plaintiffs' preliminary injunction motion prevents the Legislature from doing its job at a time that is unprecedented given the fiscal and budgetary crisis facing the State.

VI

PLAINTIFFS LACK PRUDENTIAL STANDING

There are prudential rules of standing that "apart from Article III's minimum requirements, serve to limit the role of the courts in resolving public disputes." *Warth v. Seldin*, 422 U.S. 490, 500 (1975).[10/]

In summary plaintiffs in this case are health care providers who have no "rights" under the federal law they seek to enforce. Therefore, they fail to meet the prudential rules of federal court standing.

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10. As the Supreme Court later explained the prudential rules of standing, the "judiciary seeks to avoid deciding questions of broad social import where no individual rights would be vindicated." *Gladstone Realtors v. Village of Bellwood*, 441 U.S. 91, 99-100 (1979). It is essential for standing that plaintiffs have been injured "by conduct that violates someone's . . . rights." *Id.* at 103. n.9.

CONCLUSION

The Department respectfully requests that Plaintiffs' motion for preliminary injunction be denied.

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Respectfully submitted,

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